GENICIN VITA-S- vitamin c, thiamine, riboflavin, niacin, vitamin b6, folate, vitamin b12, biotin, panothenic acid tablet

7T Pharma LLC

-----

**Genicin Vita-S** 

#### **RECOMMENDED DOSAGE:**

Usual adult dose is 1 tablet once or twice daily or as prescribed by a licensed medical practitioner. If you are pregnant or nursing, ask a healthcare professional.

**Genicin Vita-S** contains the following inactive ingredients: Microcrystalline Cellulose, Dicalcium Phosphate, Stearic Acid, Croacarmellose Sodium, and Magnesium Stearate.

## Genicin Vita-S

is an orally administered prescription vitamin formulation used for the clinical dietary management of suboptimal nutritional status in patients where advanced foliate supplementation is required and other nutritional supplementation is needed.

#### **WARNINGS:**

This product is contraindicated in patients with a known hypersensitivity to any of the ingredients.

**Genicin Vita-S** tablets should only be used under the direction and supervision of a licensed medical practitioner. Use with caution in patients that may have a medical condition, are pregnant, lactating, trying to conceive, under the age of 18, or taking medications.

## **PRECAUTIONS:**

# KEEP OUT OF REACH OF CHILDREN.

**Tamper Evident**: Do not use if seal is broken or missing.

Use with caution in patients that may have a medical condition, are pregnant, lactating, trying to conceive, under the age of 18, or taking medications.

# **Pregnancy and Lactation**

**Genicin Vita-S** is not intended for use in pregnant or lactating patients.

**Genicin Vita-S** is supplied in: 30ct bottles (70645-403-30\*) Dispensed by Prescription†

# **Dietary Supplement**

Store at 20°-25°C (68°-77°F); excursions permitted to 15°-30°C (59°-86°F) [See USP Controlled Room Temperature.]

Protect from heat, light and moisture.

- \* 7T Pharma does not represent these product codes to be National Drug Codes (NDC). Product codes are formatted according to standard industry practice, to meet the formatting requirement by pedigree reporting and supply-chain control including pharmacies.
- † This product is a prescription-folate with or without other dietary ingredients that due to increased

folate levels increased risk associated with masking of B12 deficiency (pernicious anemia) requires administration under the care of a licensed medical practitioner (61 FR 8760).<sup>1-3</sup> The most appropriate way to ensure pedigree reporting consistent with these regulatory guidelines and safety monitoring is to dispense this product only by prescription (Rx). This is not an Orange Book product. This product may be administered only under a physician's supervision and all prescriptions using this product shall be pursuant to state statutes as applicable. The ingredients, indication or claims of this product are not to be construed to be drug claims.

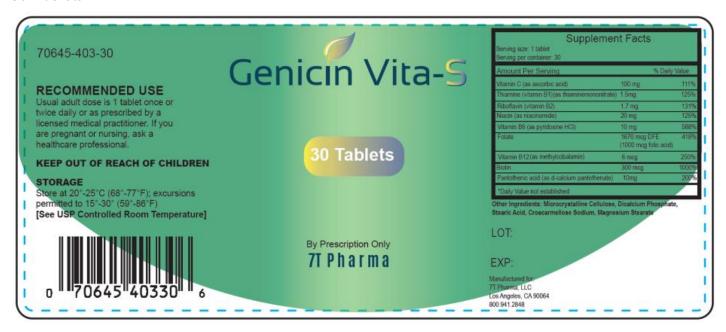
- 1. Federal Register Notice of August 2, 1973 (38 FR 20750)
- 2. Federal Register Notice of October 17, 1980 (45 FR 69043, 69044)
- 3. Federal Register Notice of March 5, 1996 (61 FR 8760)

#### Genicin Vita-S Tablets

Manufactured for: 7T Pharma, LLC Los Angeles, CA 90064 800.941.2848

## PRINCIPAL DISPLAY PANEL

NDC 70645-403-30 Genicin Vita-S 30 Tablets



## **GENICIN VITA-S**

vitamin c, thiamine, riboflavin, niacin, vitamin b6, folate, vitamin b12, biotin, panothenic acid tablet

Product Information			
Product Type	DIETARY SUPPLEMENT	Item Code (Source)	NHRIC:70645-403
Route of Administration	ORAL		

# **Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
ASCORBIC ACID (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	100 mg
THIAMINE (UNII: X66NSO3N35) (THIAMINE ION - UNII:4ABT0J945J)	THIAMINE	1.5 mg
RIBOFLAVIN (UNII: TLM2976OFR) (RIBOFLAVIN - UNII:TLM2976OFR)	RIBOFLAVIN	1.7 mg
NIACIN (UNII: 2679 MF687A) (NIACIN - UNII:2679 MF687A)	NIACIN	20 mg
<b>PYRIDO XINE HYDRO CHLO RIDE</b> (UNII: 68 Y4CF58 BV) (PYRIDO XINE - UNII: KV2JZ1BI6 Z)	PYRIDO XINE HYDROCHLO RIDE	10 mg
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	1000 ug
METHYLCOBALAMIN (UNII: BR1SN1JS2W) (METHYLCOBALAMIN - UNII:BR1SN1JS2W)	METHYLCOBALAMIN	6 ug
<b>BIOTIN</b> (UNII: 6SO6U10H04) (BIOTIN - UNII:6SO6U10H04)	BIOTIN	300 ug
PANTOTHENIC ACID (UNII: 19 F5HK2737) (PANTOTHENIC ACID - UNII:19 F5HK2737)	PANTOTHENIC ACID	10 mg

Inactive Ingredients		
Ingredient Name	Strength	
MICRO CRYSTALLINE CELLULO SE (UNII: OP1R32D61U)		
DIBASIC CALCIUM PHO SPHATE DIHYDRATE (UNII: O7TSZ97GEP)		
STEARIC ACID (UNII: 4ELV7Z65AP)		
CROSCARMELLOSE SODIUM (UNII: M28 OL1HH48)		
MAGNESIUM STEARATE (UNII: 70097M6I30)		

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NHRIC:70645-403-30	30 in 1 BOTTLE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
DIETARY SUPPLEMENT		10 /0 1/20 18	

Supplement Facts			
Serving Size :		Serving per Container :	
	<b>Amount Per Serving</b>	% Daily Value	
color			
scoring	1		
shape			
size (solid drugs)	5 mm		

# **Labeler -** 7T Pharma LLC (080220022)

Revised: 10/2018 7T Pharma LLC